

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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1) \_\_\_\_\_  
2) \_\_\_\_\_  
3) \_\_\_\_\_  
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DOCKETED BY: *PM*  
DATE: *5-10-06*

## PCT

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

05 MAY 2006

Applicant's or agent's file reference

689290.163

**IMPORTANT NOTIFICATION**

International application No.

PCT/US03/17592

International filing date (day/month/year)

05 June 2003 (05.06.2003)

Priority date (day/month/year)

07 June 2002 (07.06.2002)

Applicant

RICK ET AL.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

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*Minh Tam Davis*  
MINH TAM DAVIS

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Form PCT/IPEA/416 (July 1992)

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 689290.163	<div style="display: flex; justify-content: space-between;"> <div> <b>FOR FURTHER ACTION</b> </div> <div>           See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)         </div> </div>	
International application No. PCT/US03/17592	International filing date (day/month/year) 05 June 2003 (05.06.2003)	Priority date (day/month/year) 07 June 2002 (07.06.2002)
International Patent Classification (IPC) or national classification and IPC IPC: C12Q 1/68( 2006.01) USPC: 435/6		
Applicant RICK ET AL.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>—</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>		
Date of submission of the demand 05 June 2003 (05.06.2003)	Date of completion of this report 14 April 2006 (14.04.2006)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	<div style="display: flex; align-items: center;"> <div style="flex: 1;">           Authorized Officer            MINE TAM DAVIS         </div> <div style="flex: 2; text-align: center;"> </div> </div> Telephone No. 571-272-1642	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/17592

**I. Basis of the report**

## 1. With regard to the elements of the international application: \*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-41 as originally filed  
pages NONE filed with the demand  
pages NONE filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 42-46 as originally filed  
pages NONE as amended (together with any statement) under Article 19  
pages NONE filed with the demand  
pages NONE filed with the letter of \_\_\_\_\_.
- ☐ the drawings:  
pages NONE as originally filed  
pages NONE filed with the demand  
pages NONE filed with the letter of \_\_\_\_\_.
- ☒ the sequence listing part of the description:  
pages 1-5 as originally filed  
pages NONE filed with the demand  
pages NONE filed with the letter of \_\_\_\_\_.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)). \*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/17592

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 9-35

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-35

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/17592**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>2 and 4</u>	YES
	Claims <u>1,3,5-8 and 36</u>	NO
Inventive Step (IS)	Claims <u>2 and 4</u>	YES
	Claims <u>1,3,5-8 and 36</u>	NO
Industrial Applicability (IA)	Claims <u>1-8, 36</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1, 3, 5-8, 36 lack novelty under PCT Article 33(2) as being anticipated by US 5,914,269.

US 5,914,269 teaches screening assays to identify and determine the ability of a candidate antisense molecule to decrease the expression of EGFR gene in cancer cells (Summary and Example 8). US 5,914,269 teaches methods of modulating expression of EGFR in tissues, or in vivo, using said antisense (Summary).

It is noted that in view of a lack of a definition of "corresponds", any gene would correspond to SEQ ID NO:1.

Although the reference does not specifically teach that EGFR gene corresponds to SEQ ID NO:1, however, the claimed target gene for use in the claimed method appears to be the same as the prior art gene. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences.

Thus, the method taught by US 5,968,737 seems to be the same as the claimed method.

Claims 2,4 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for screening an agent that modulates the activity of SEQ ID NO:1 in a cell, which could be a kidney cancer cell.